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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/380,579	09/07/99	IKEHARA	S 055691

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EXAMINER	
VANDER VEGT,F	
ART UNIT	**PAPER NUMBER**
1644	9

DATE MAILED: 07/16/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/380,579	Applicant(s) Ikehara et al
	Examiner F. Pierre VanderVegt	Art Unit 1644

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) [X] Responsive to communication(s) filed on *May 1, 2001*

2a) [X] This action is **FINAL.** 2b) [ ] This action is non-final.

3) [ ] Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) [X] Claim(s) *9-12* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideratio

5) [ ] Claim(s) _____ is/are allowed.

6) [X] Claim(s) *9-12* is/are rejected.

7) [ ] Claim(s) _____ is/are objected to.

8) [ ] Claims _____ are subject to restriction and/or election requirement

Application Papers

9) [ ] The specification is objected to by the Examiner.

10) [ ] The drawing(s) filed on _____ is/are objected to by the Examiner.

11) [ ] The proposed drawing correction filed on _____ is: a) [ ] approved b) [ ] disapproved.

12) [ ] The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) [ ] Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) [ ] All b) [ ] Some* c) [ ] None of:

1. [ ] Certified copies of the priority documents have been received.
2. [ ] Certified copies of the priority documents have been received in Application No. _____.
3. [ ] Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) [ ] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) [ ] Notice of References Cited (PTO-892)

16) [ ] Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) [ ] Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) [ ] Interview Summary (PTO-413) Paper No(s). _____

19) [ ] Notice of Informal Patent Application (PTO-152)

20) [ ] Other:

DETAILED ACTION

This application is a rule 371 continuation of PCT application PCT/JP98/00909.

Claims 1-8 have been canceled.

New claims 9-12 have been added and are currently pending in this application.

Specification

1. A substitute specification, excluding claims, in proper idiomatic English and in compliance with 37 CFR 1.52(a) and (b) is required. The substitute specification filed must be accompanied by a statement that it contains no new matter.

The specification appears to be a near literal translation from Japanese. A substitute specification in grammatically correct English is required.

2. In view of the amendment filed May 1, 2001, no outstanding rejections are maintained. **The following new ground of rejection was necessitated by Applicant's amendment.**

Claim Rejections - 35 U.S.C. § 112

3. Claim 10 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 10 recites the limitation "in the range of 6.5 Gy to 7.0 Gy" in line 2 of the claim. Applicant asserts that support for said amendment is found at page 14, lines 7-16 of the instant specification. However, the disclosure there recites only doses of 6.5 and 7.0 Gy, not a range of 6.5 to 7.0. Further, the specification at page 14, lines 9-11 recite "at least 6.5 Gy and yet sublethal dose, preferably about 7.0 Gy." Reciting "at least 6.5" and "about 7.0" does not support reciting a range of 6.5 to 7.0. The instant specification at no point discloses a range of 6.5 to 7.0 Gy and the recitation thereof therefore constitutes new matter.

4. Claims 9-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for effectively inducing immunotolerance in a mouse, does not reasonably provide enablement for larger organ transplant recipients, such as a human. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Briefly, the claims are drawn to the induction of immunotolerance in an organ transplant recipient by irradiating the recipient with at least 6.5 Gy of sublethal irradiation followed by donor whole bone marrow infusion into the hepatic portal vein and the organ transplant. While the instant specification has clearly enabled the use of at least 6.5 Gy of irradiation in mice for effective treatment, the specification lacks guidance regarding the level of sublethal radiation which would be effective in a human, for example, which is a mammal with a great deal more body mass. Clearly, the step of sublethally irradiating the recipient must have some effect upon some recipient cell population(s) or cellular process(es). However, the specification fails to disclose any type of measurable property or process induced in the mouse, such as enhancement or inhibition of cell proliferation or changes in cytokine levels as examples, other than the end result of enhanced graft tolerance. Without such a measurable property which can be correlated to level of sublethal irradiation, it would require an undue level of trial and error on the part of the artisan to practice the invention with the only indication of effective radiation being the final success or failure of the graft in a proportion of subjects. It is not readily apparent for the instant specification that such a determination would be within the purview of the ordinary practitioner.

In view of the nature of the invention, the level of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims, it would take undue trials and errors to practice the claimed invention and this is not sanctioned by the statute.

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

6. Papers related to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax phone number for official documents to be entered into the record for Art Unit 1644 is (703)305-3014.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to F. Pierre VanderVegt, whose telephone number is (703)305-6997. The Examiner can normally be reached Tuesday through Friday and odd-numbered Mondays (on year 2001 365-day calender) from 6:30 am to 4:00 pm ET. A message may be left on the Examiner's voice mail service. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ms. Christina Chan can be reached at (703)308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist, whose telephone number is (703)308-0196.

F. Pierre VanderVegt, Ph.D.
Patent Examiner
Technology Center 1600
July 11, 2001

CHRISTINA Y. CHAN
SUPERVISORY PATENT EXAMINER
GROUP ~~1800~~ 1640